MAR 2 8 2005

K042626

510(K) SUMMARY
NeuroPort™ NSP System

Submitter Name:	Cyberkinetics, Inc.
Submitter Address:	100 Foxborough Boulevard, Suite 240 Foxboro, MA 02035
Contact Person:	Nandini Murthy, V.P. Regulatory Affairs and Quality Systems
Phone Number:	(508) 549-9981, Extn 103
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Date Prepared:	Sept 24, 2004
Device Trade Name:	NeuroPort™ NSP System
Device Common Name:	Neural Signal Amplifier
Predicate Devices:	BMSI 5000 (Nicolet), Ceegraph (Bio-Logic) and EMU 128 (XLTek)
Device Description:	The Neuroport Neural Signal Processing (NSP) System is intended for recording and monitoring. Its functionality includes routine brain activity recording, monitoring, retrieval and replay. The Neuroport supports up to 96 channels of recording and is comprised of the following hardware components: Patient Cable, Amplifier, CPU and a Display monitor. The Neuroport System also includes the following software functions: acquisition, amplification and display.
Intended Use:	The NeuroPort™ NSP System is intended for temporary (<30 days) recording and monitoring of brain electrical activity.
Performance Data:	The NeuroPort™ NSP conforms to the relevant safety standards for intra-operative and hospital monitoring settings: IEC 60601-2-26, IEC 60601-1-2, UL 2601-1, CAN/CSA-C22.2 no. 601.1-M90.
Conclusion:	The NeuroPort™ Neural Signal Processing (NSP) System has similar indications statements as the predicate devices. All are used for monitoring brain electrical activity. The functionality of the Neuroport NSP System and predicate devices is identical and includes routine brain activity recording, amplification, digitization, monitoring, retrieval and display. Therefore the Neuroport NSP is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cyberkinetics, Inc.
c/o Ms. Nandini Murthy
Vice President, Vice President Regulatory Affairs
and Quality Systems
100 Foxborough Boulevard, Suite 240
Foxborough, Massachusetts 02035

APR - 9 2012

Re: K042626
Trade/Device Name: Neuroport™ Neural Signal Processor System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated (Date on orig SE ltr): February 8, 2005
Received (Date on orig SE ltr): February 9, 2005

Dear Ms. Murthy:

This letter corrects our substantially equivalent letter of March 28, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042626

Device Name: Neuroport™ Neural Signal Processor System

Indications For Use:

The intended use of the Cyberkinetics, Inc. Neuroport Neural Signal Processor System is for temporary (<30 days) recording and monitoring of brain electrical activity.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042626